IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH LLC, Plaintiff, v. NOSTRUM PHARMACEUTICALS, LLC, NOSTRUM LABORATORIES, INC., and ENEM NOSTRUM REMEDIES PVT. LTD., Defendants.	Civil Action No. 3:11-cv-02280-JAP -LHG

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Wyeth LLC ("Wyeth") for its First Amended Complaint against Defendants Nostrum Pharmaceuticals, LLC, Nostrum Laboratories, Inc., and Enem Nostrum Remedies Pvt. Ltd. (collectively "Nostrum") hereby states as follows:

THE PARTIES

1. Plaintiff Wyeth is a Delaware limited liability company with a place of business at Five Giralda Farms, Madison, New Jersey 07940. Plaintiff Wyeth is an indirect wholly owned subsidiary of Pfizer Inc., a Delaware corporation.

2. On information and belief, Defendant Nostrum Pharmaceuticals, LLC ("Nostrum Pharms") is a limited liability company, organized and existing under the state of Delaware, having its principal place of business at 11D Jules Lane, New Brunswick, New Jersey 08901.

3. On information and belief, Defendant Nostrum Laboratories, Inc. ("Nostrum Labs") is a corporation, organized and existing under the state of New Jersey, having its principal place of business at 1800 N. Topping Ave, Kansas City, Missouri 64120-1228.

4. On information and belief, Defendant Enem Nostrum Remedies Pvt. Ltd. ("Enem Nostrum"), is a limited liability company, organized and existing under the laws of India, having

its principal place of business at 201-204 Gayatri Commercial Complex, Behind Mittal Industrial Estate, Marol, Andheri (East), Maharashtra, India.

5. On information and belief, Nostrum Pharms directly and/or through its wholly-owned subsidiaries, develops, manufactures, distributes, sells, and markets generic drug products for sale and use throughout the United States, including within this judicial district.

6. On information and belief, Nostrum Labs is a wholly-owned subsidiary of Nostrum Pharms controlled and/or dominated by Nostrum Pharms.

7. On information and belief, Nostrum Labs develops, manufactures, distributes, sells, and markets generic drug products for sale and use throughout the United States, including within this judicial district.

8. On information and belief, Enem Nostrum is a wholly-owned subsidiary of Nostrum Pharms controlled and/or dominated by Nostrum Pharms.

9. On information and belief, Enem Nostrum develops, manufactures, distributes, sells, and markets generic drug products for sale and use throughout the United States, including within this judicial district.

10. On information and belief, Nostrum Pharms operates through its wholly owned subsidiary and agent, Nostrum Labs.

11. On information and belief, Nostrum Pharms operates through its wholly owned subsidiary and agent, Enem Nostrum.

12. On information and belief, Nostrum Pharms, Nostrum Labs and Enem Nostrum have common officers and directors, and have represented to the public that they are a unitary entity.

13. On information and belief, the acts of Nostrum Pharms complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of Nostrum Labs and/or Enem Nostrum.

14. On information and belief, the acts of Nostrum Labs complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of Nostrum Pharms and/or Enem Nostrum.

15. On information and belief, the acts of Enem Nostrum complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of Nostrum Labs and/or Nostrum Pharms.

NATURE OF THE ACTION

16. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 200-430, including any and all amendments thereto, submitted by Nostrum to the United States Food and Drug Administration ("FDA") for approval to market generic copies of Wyeth's highly successful EFFEXOR® XR pharmaceutical products that are sold in the United States.

JURISDICTION AND VENUE

17. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

18. On information and belief, Nostrum is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling and commercializing pharmaceutical products. Nostrum maintains a website at the uniform resource locator (URL) http://www.nostrumpharma.com ("the Nostrum website"). According to that website, Nostrum "is engaged in the formulation and commercialization of specialty pharmaceutical products and controlled-release, orally-administered, branded and generic drugs." Moreover, the Nostrum

website states that "Nostrum[] [Pharms'] rich portfolio is supported by research and development in India through its Enem Nostrum facility as well as technology transfer and production at its Nostrum Laboratories, Inc facility in Kansas City, MO."

19. On information and belief, Nostrum Pharms, either directly or through one or more of its wholly owned subsidiaries and/or agents — including Nostrum Labs and/or Enem Nostrum — develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

20. On information and belief, Nostrum Labs, with the assistance and/or at the direction of Nostrum Pharms and/or Enem Nostrum, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

21. On information and belief, Enem Nostrum, with the assistance and/or at the direction of Nostrum Pharms and/or Nostrum Labs, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

22. On information and belief, Nostrum Pharms, Nostrum Labs, and Enem Nostrum operate as an integrated, unitary business.

23. On information and belief, Nostrum has generated significant revenue from purchases made by Nostrum's prescription drug product customers, who are located throughout the United States, including within this judicial district.

24. On information and belief, Nostrum Pharms, Nostrum Labs, and Enem Nostrum acted in concert to develop Nostrum's generic copies of Wyeth's EFFEXOR® XR Capsules and

to seek approval from the FDA to sell Nostrum's generic copies of Wyeth's EFFEXOR® XR Capsules throughout the United States and in this judicial district.

25. On information and belief, Nostrum Pharms and/or one or more of its wholly owned subsidiaries and/or agents, including Nostrum Labs and/or Enem Nostrum, submitted ANDA No. 200-430, including any and all amendments thereto, to the FDA. On information and belief, Nostrum Pharms has attributed the acts of Nostrum Labs and/or Enem Nostrum to itself. Moreover, on information and belief, Nostrum Labs and/or Enem Nostrum have attributed the acts of Nostrum Pharms to themselves. On information and belief, Nostrum Pharms, Nostrum Labs, and Enem Nostrum thus acted as a single entity in connection with the preparation and submission of ANDA No. 200-430.

26. On information and belief, and as previously noted, Nostrum Labs is a corporation organized and existing under the laws of New Jersey, and by virtue of its incorporation in New Jersey, this Court has personal jurisdiction over Nostrum Labs.

27. On information and belief, by virtue of, *inter alia*, Nostrum Labs' relationship with Nostrum Pharms in connection with the preparation and/or filing of ANDA No. 200-430, including any and all amendments thereto, and their systematic and continuous activities in New Jersey, including but not limited to the development of generic drug products for sale to residents of New Jersey, this Court has personal jurisdiction over Nostrum Pharms.

28. On information and belief, by virtue of, *inter alia*, Nostrum Labs' relationship with Enem Nostrum in connection with the preparation and/or filing of ANDA No. 200-430, including any and all amendments thereto, and their systematic and continuous activities in New Jersey, including but not limited to the development of generic drug products for sale to residents of New Jersey, this Court has personal jurisdiction over Enem Nostrum.

29. On information and belief, separate and apart from its relationship with Nostrum Labs and Enem Nostrum, Nostrum Pharms has availed itself of the laws of the State of New Jersey and engaged in a course of conduct in the State of New Jersey, by at least maintaining a place of business in New Jersey and incorporating and/or maintaining the incorporation of its subsidiary and/or agent, Nostrum Labs, under New Jersey law, and identifying the Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628 as the registered agent of Nostrum Labs. On information and belief, this Court also has personal jurisdiction over Nostrum Pharms due to the continuous presence of Nostrum Pharms' facilities and employees in New Jersey.

30. On information and belief, by virtue of, *inter alia*, Nostrum's continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions Nostrum Pharms, Nostrum Labs, and Enem Nostrum in connection with ANDA No. 200-430, as well as any and all amendments thereto, this Court has personal jurisdiction over Nostrum Pharms, Nostrum Labs, and Enem Nostrum. These activities satisfy due process and confer personal jurisdiction over Nostrum consistent with the New Jersey long arm statute.

31. On information and belief, if Enem Nostrum is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, it likewise would not be subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amendable to personal jurisdiction and service of process based on its aggregate contacts with the United States, including but not limited to the above-described contacts, as authorized by Federal Rule of Civil Procedure 4(k)(2).

32. Venue is proper in this judicial district under 28 U.S.C. § 1391(b), (c) and/or (d) and/or 28 U.S.C. § 1400(b).

BACKGROUND

33. Wyeth Pharmaceuticals Inc. is the holder of approved New Drug Application ("NDA") No. 20-699 for EFFEXOR® XR Capsules, an extended release dosage form containing venlafaxine hydrochloride. Wyeth Pharmaceuticals Inc. is a wholly owned indirect subsidiary of Pfizer Inc.

34. On information and belief, Nostrum submitted to the FDA ANDA No. 200-430 under 21 U.S.C. § 355(j), and subsequently amended ANDA No. 200-430 under 21 U.S.C. § 355(j), to seek approval to market Venlafaxine Hydrochloride 37.5 mg, 75 mg, and 150 mg Extended-Release Capsules ("Nostrum's Venlafaxine Hydrochloride ER Capsules"), which are generic copies of Wyeth's EFFEXOR® XR Capsules in 37.5 mg, 75 mg, and 150 mg dosage strengths, respectively.

35. By letters dated March 8, 2011, Nostrum notified Wyeth that it had submitted ANDA No. 200-430, seeking approval to market its 150 mg Venlafaxine Hydrochloride ER Capsules, and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B). Wyeth received these letters on or about March 14, 2011.

36. By letters dated June 3, 2011, Nostrum notified Wyeth that it had amended ANDA No. 200-430, that it was seeking approval to market 37.5 mg and 75 mg Venlafaxine Hydrochloride ER Capsules in addition to its 150 mg Venlafaxine Hydrochloride ER Capsules, and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B). Wyeth received these letters on or about June 11, 2011.

FIRST COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,274,171 B1

37. Wyeth incorporates by reference paragraphs 1-36 of this First Amended Complaint as if fully set forth herein.

38. United States Patent No. 6,274,171 B1 ("the '171 Patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was duly and legally issued by the United States Patent and Trademark Office on August 14, 2001. Wyeth (formerly known as American Home Products Corporation) is the owner by assignment of the '171 Patent and has the right to sue for infringement thereof. A true and correct copy of the '171 Patent is attached as Exhibit A.

39. On information and belief, Nostrum submitted and amended ANDA No. 200-430 in order to obtain approval to market Nostrum's Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '171 Patent. On information and belief, Nostrum also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetics Act), a certification alleging that the claims of the '171 Patent are invalid and/or not infringed. On information and belief, Nostrum amended this certification to state and/or submitted additional certifications stating that the claims of the '171 Patent are invalid and/or not infringed by any dosage strength associated with Nostrum's Venlafaxine Hydrochloride ER Capsules.

40. Under 35 U.S.C. § 271(e)(2)(A), Nostrum's submission to the FDA of ANDA No. 200-430, including any and all amendments thereto, to obtain approval for the commercial manufacture, use, or sale of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration date of the '171 Patent constitutes infringement of one or more claims of the '171 Patent, either literally or under the doctrine of equivalents.

41. Upon FDA approval of Nostrum's ANDA No. 200-430, Nostrum will infringe the '171 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Nostrum's Venlafaxine Hydrochloride ER Capsules in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C.

§§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Nostrum's ANDA shall be no earlier than the expiration date of the '171 Patent and any additional periods of exclusivity.

42. On information and belief, Nostrum's Venlafaxine Hydrochloride ER Capsules, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '171 Patent, either literally or under the doctrine of equivalents.

43. On information and belief, the use of Nostrum's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '171 Patent; Nostrum knows that its Venlafaxine Hydrochloride ER Capsules are especially made or adapted for use in infringing at least one of the claims of the '171 Patent, either literally or under the doctrine of equivalents; and Nostrum's Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

44. On information and belief, the offering to sell, sale, and/or importation of Nostrum's Venlafaxine Hydrochloride ER Capsules would contributorily infringe at least one of the claims of the '171 Patent, either literally or under the doctrine of equivalents.

45. On information and belief, Nostrum had knowledge of the '171 Patent and, by its promotional activities and package insert for Nostrum's Venlafaxine Hydrochloride ER Capsules, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '171 Patent, either literally or under the doctrine of equivalents.

46. On information and belief, the offering to sell, sale, and/or importation of Nostrum's Venlafaxine Hydrochloride ER Capsules would actively induce infringement of at least one of the claims of the '171 Patent, either literally or under the doctrine of equivalents.

47. Wyeth will be substantially and irreparably harmed by Nostrum's infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

SECOND COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,403,120 B1

48. Wyeth incorporates by reference paragraphs 1-36 of this First Amended Complaint as if fully set forth herein.

49. United States Patent No. 6,403,120 B1 ("the '120 Patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was duly and legally issued by the United States Patent and Trademark Office on June 11, 2002. Wyeth is the owner by assignment of the '120 Patent and has the right to sue for infringement thereof. A true and correct copy of the '120 Patent is attached as Exhibit B.

50. On information and belief, Nostrum submitted and amended ANDA No. 200-430 in order to obtain approval to market Nostrum's Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '120 Patent. On information and belief, Nostrum also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '120 Patent are invalid and/or not infringed. On information and belief, Nostrum amended this certification to state and/or submitted additional certifications stating that the claims of the '120 Patent are invalid and/or not infringed by any dosage strength associated with Nostrum's Venlafaxine Hydrochloride ER Capsules.

51. Under 35 U.S.C. § 271(e)(2)(A), Nostrum's submission to the FDA of ANDA No. 200-430, including any and all amendments thereto, to obtain approval for the commercial manufacture, use, or sale of Nostrum's Venlafaxine Hydrochloride ER Capsules before the

expiration date of the ‘120 Patent constitutes infringement of one or more claims of the ‘120 Patent, either literally or under the doctrine of equivalents.

52. Upon FDA approval of Nostrum’s ANDA No. 200-430, Nostrum will infringe the ‘120 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Nostrum’s Venlafaxine Hydrochloride ER Capsules in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Nostrum’s ANDA shall be no earlier than the expiration of the ‘120 Patent and any additional periods of exclusivity.

53. On information and belief, Nostrum’s Venlafaxine Hydrochloride ER Capsules, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘120 Patent, either literally or under the doctrine of equivalents.

54. On information and belief, the use of Nostrum’s Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the ‘120 Patent; Nostrum knows that Nostrum’s Venlafaxine Hydrochloride ER Capsules are especially made or adapted for use in infringing at least one of the claims of the ‘120 Patent, either literally or under the doctrine of equivalents; and Nostrum’s Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

55. On information and belief, the offering to sell, sale, and/or importation of Nostrum’s Venlafaxine Hydrochloride ER Capsules would contributorily infringe at least one of the claims of the ‘120 Patent, either literally or under the doctrine of equivalents.

56. On information and belief, Nostrum had knowledge of the '120 Patent and, by its promotional activities and package insert for Nostrum's Venlafaxine Hydrochloride ER Capsules, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '120 Patent, either literally or under the doctrine of equivalents.

57. On information and belief, the offering to sell, sale, and/or importation of Nostrum's Venlafaxine Hydrochloride ER Capsules would actively induce infringement of at least one of the claims of the '120 Patent, either literally or under the doctrine of equivalents.

58. Wyeth will be substantially and irreparably harmed by Nostrum's infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

THIRD COUNT FOR INFRINGEMENT
OF UNITED STATES PATENT NO. 6,419,958 B2

59. Wyeth incorporates by reference paragraphs 1-36 of this First Amended Complaint as if fully set forth herein.

60. United States Patent No. 6,419,958 B2 ("the '958 Patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was duly and legally issued by the United States Patent and Trademark Office on July 16, 2002. Wyeth is the owner by assignment of the '958 Patent and has the right to sue for infringement thereof. A true and correct copy of the '958 Patent is attached as Exhibit C.

61. On information and belief, Nostrum submitted and amended ANDA No. 200-430 in order to obtain approval to market Nostrum's Venlafaxine Hydrochloride ER Capsules in the United States before the expiration of the '958 Patent. On information and belief, Nostrum also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '958 Patent are invalid and/or not infringed. On information and belief, Nostrum

amended this certification to state and/or submitted additional certifications stating that the claims of the '958 Patent are invalid and/or not infringed by any dosage strength associated with Nostrum's Venlafaxine Hydrochloride ER Capsules.

62. Under 35 U.S.C. § 271(e)(2)(A), Nostrum's submission to the FDA of ANDA No. 200-430, including any and all amendments thereto, to obtain approval for the commercial manufacture, use, or sale of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration date of the '958 Patent constitutes infringement of one or more claims of the '958 Patent, either literally or under the doctrine of equivalents.

63. Upon FDA approval of Nostrum's ANDA No. 200-430, Nostrum will infringe the '958 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Nostrum's Venlafaxine Hydrochloride ER Capsules in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of Nostrum's ANDA shall be no earlier than the expiration date of the '958 Patent and any additional periods of exclusivity.

64. On information and belief, Nostrum's Venlafaxine Hydrochloride ER Capsules, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '958 Patent, either literally or under the doctrine of equivalents.

65. On information and belief, the use of Nostrum's Venlafaxine Hydrochloride ER Capsules constitutes a material part of at least one of the claims of the '958 Patent; Nostrum knows that its Venlafaxine Hydrochloride ER Capsules are especially made or adapted for use in infringing at least one of the claims of the '958 Patent, either literally or under the doctrine of

equivalents; and Nostrum's Venlafaxine Hydrochloride ER Capsules are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

66. On information and belief, the offering to sell, sale, and/or importation of Nostrum's Venlafaxine Hydrochloride ER Capsules would contributorily infringe at least one of the claims of the '958 Patent, either literally or under the doctrine of equivalents.

67. On information and belief, Nostrum had knowledge of the '958 Patent and, by its promotional activities and package insert for Nostrum's Venlafaxine Hydrochloride ER Capsules, will know or should know that it will aid and abet another's direct infringement of at least one of the claims of the '958 Patent, either literally or under the doctrine of equivalents.

68. On information and belief, the offering to sell, sale, and/or importation of Nostrum's Venlafaxine Hydrochloride ER Capsules would actively induce infringement of at least one of the claims of the '958 Patent, either literally or under the doctrine of equivalents.

69. Wyeth will be substantially and irreparably harmed by Nostrum's infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

FOURTH COUNT FOR INFRINGEMENT OF
UNITED STATES PATENT NOS. 6,274,171 B1, 6,403,120 B1, AND 6,419,958 B2

(By Nostrum Pharms)

70. Wyeth incorporates by reference paragraphs 1 through 69 and 74 to 81 of this First Amended Complaint as if fully set forth herein.

71. On information and belief, Nostrum Pharms actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 200-430, including any and all amendments thereto, to the FDA. On information and belief,

Nostrum Pharms was aware of the '171 Patent, the '120 Patent, and the '958 Patent when it engaged in these knowing and purposeful activities referred to above.

72. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Nostrum Pharms induced the infringement of the '171 Patent, the '120 Patent, and the '958 Patent by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 200-430, including any and all amendments thereto. The filing of the ANDA and the amendments thereto by Nostrum Pharms, Nostrum Labs, and/or Enem Nostrum constitutes direct infringement under 35 U.S.C. § 271(e). Nostrum Pharms' active and knowing aiding and abetting Nostrum Labs, and/or Enem Nostrum in the filing of ANDA No. 200-430 and the amendments thereto constitute induced infringement.

73. Wyeth will be substantially and irreparably harmed by Nostrum Pharms' infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

FIFTH COUNT FOR INFRINGEMENT OF
UNITED STATES PATENT NOS. 6,274,171 B1, 6,403,120 B1, AND 6,419,958 B2

(By Nostrum Labs)

74. Wyeth incorporates by reference paragraphs 1 through 73 and 78 through 81 of this First Amended Complaint as if fully set forth herein.

75. On information and belief, Nostrum Labs actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 200-430, including any and all amendments thereto, to the FDA. On information and belief, Nostrum Labs was aware of the '171 Patent, the '120 Patent, and the '958 Patent when it engaged in these knowing and purposeful activities referred to above.

76. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Nostrum Labs induced the infringement of the '171 Patent, the '120 Patent, and the '958 Patent by actively and knowingly

aiding and abetting the submission to the FDA of ANDA No. 200-430, including any and all amendments thereto. The filing of the ANDA and the amendments thereto by Nostrum Pharms, Nostrum Labs, and/or Enem Nostrum constitutes direct infringement under 35 U.S.C. § 271(e). Nostrum Labs' active and knowing aiding and abetting Nostrum Pharms and Enem Nostrum in the filing of ANDA No. 200-430 and the amendments thereto constitute induced infringement.

77. Wyeth will be substantially and irreparably harmed by Nostrum Labs' infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

SIXTH COUNT FOR INFRINGEMENT OF
UNITED STATES PATENT NOS. 6,274,171 B1, 6,403,120 B1, AND 6,419,958 B2

(By Enem Nostrum)

78. Wyeth incorporates by reference paragraphs 1 through 77 of this First Amended Complaint as if fully set forth herein.

79. On information and belief, Enem Nostrum actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 200-430, including any and all amendments thereto, to the FDA. On information and belief, Enem Nostrum was aware of the '171 Patent, the '120 Patent, and the '958 Patent when it engaged in these knowing and purposeful activities referred to above.

80. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Enem Nostrum induced the infringement of the '171 Patent, the '120 Patent, and the '958 Patent by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 200-430, including any and all amendments thereto. The filing of the ANDA and the amendments thereto by Nostrum Pharms, Nostrum Labs, and/or Enem Nostrum constitutes direct infringement under 35 U.S.C. § 271(e).

Enem Nostrum's active and knowing aiding and abetting Nostrum Pharms and Nostrum Labs in the filing of ANDA No. 200-430 and the amendments thereto constitute induced infringement.

81. Wyeth will be substantially and irreparably harmed by Enem Nostrum's infringing activities unless those activities are enjoined by this Court. Wyeth has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Wyeth respectfully requests that this Court enter judgment in its favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Nostrum's submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '171 Patent was an act of infringement of the '171 Patent;

(2) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Nostrum Pharms' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '171 Patent was an act of induced infringement of the '171 Patent;

(3) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Nostrum Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER

Capsules before the expiration of the '171 Patent was an act of induced infringement of the '171 Patent;

(4) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Enem Nostrum's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '171 Patent was an act of induced infringement of the '171 Patent;

(5) declaring that Nostrum's commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Nostrum of Nostrum's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '171 Patent;

(6) declaring that, under 35 U.S.C. § 271(e)(2)(A), Nostrum's submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 Patent was an act of infringement of the '120 Patent;

(7) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Nostrum Pharms' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 Patent was an act of induced infringement of the '120 Patent;

(8) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Nostrum Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 Patent was an act of induced infringement of the '120 Patent;

(9) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Enem Nostrum's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '120 Patent was an act of induced infringement of the '120 Patent;

(10) declaring that Nostrum's commercial manufacture, use, offer for sale or sale in, or importation into the United States by Nostrum of Nostrum's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '120 Patent;

(11) declaring that, under 35 U.S.C. § 271(e)(2)(A), Nostrum's submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 Patent was an act of infringement of the '958 Patent;

(12) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Nostrum Pharms' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for

sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 Patent was an act of induced infringement of the '958 Patent;

(13) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Nostrum Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 Patent was an act of induced infringement of the '958 Patent;

(14) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Enem Nostrum's active and knowing aiding and abetting of the submission to the FDA of ANDA No. 200-430 and the amendments thereto to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Nostrum's Venlafaxine Hydrochloride ER Capsules before the expiration of the '958 Patent was an act of induced infringement of the '958 Patent;

(15) declaring that Nostrum's commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Nostrum of Nostrum's Venlafaxine Hydrochloride ER Capsules would constitute infringement of the '958 Patent;

(16) ordering that the effective date of any FDA approval of Nostrum's Venlafaxine Hydrochloride ER Capsules shall be no earlier than the expiration date of the '171 Patent and any additional dates of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(17) ordering that the effective date of any FDA approval of Nostrum's Venlafaxine Hydrochloride ER Capsules shall be no earlier than the expiration date of the '120 Patent and any additional dates of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(18) ordering that the effective date of any FDA approval of Nostrum's Venlafaxine Hydrochloride ER Capsules shall be no earlier than the expiration date of the '958 Patent and any additional dates of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(19) enjoining Nostrum and all persons acting in concert with Nostrum, from commercially manufacturing, using, offering for sale, or selling Nostrum's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Nostrum's Venlafaxine Hydrochloride ER Capsules, until the expiration of the '171 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(20) enjoining Nostrum and all persons acting in concert with Nostrum from commercially manufacturing, using, offering for sale or selling Nostrum's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Nostrum's Venlafaxine Hydrochloride ER Capsules until the expiration of the '120 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(21) enjoining Nostrum and all persons acting in concert with Nostrum from commercially manufacturing, using, offering for sale, or selling Nostrum's Venlafaxine Hydrochloride ER Capsules within the United States or importing into the United States Nostrum's Venlafaxine Hydrochloride ER Capsules, until the expiration of the '958 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(22) enjoining Nostrum and all persons acting in concert with Nostrum from seeking, obtaining, or maintaining approval of Nostrum's ANDA No. 200-430, including any and all amendments thereto, until the expiration of the '171 Patent;

(23) enjoining Nostrum and all persons acting in concert with Nostrum from seeking, obtaining, or maintaining approval of Nostrum's ANDA No. 200-430, including any and all amendments thereto, until the expiration of the '120 Patent;

(24) enjoining Nostrum and all persons acting in concert with Nostrum from seeking, obtaining, or maintaining approval of Nostrum's ANDA No. 200-430, including any and all amendments thereto, until the expiration of the '958 Patent;

(25) declaring this to be an exceptional case and awarding Wyeth its attorney fees under 35 U.S.C. § 285;

(26) awarding Wyeth its costs and expenses in this action; and

(27) awarding Wyeth any further and additional relief as this Court deems just and proper.

Dated: July 15, 1011

Respectfully Submitted,

BY: /s *Liza M. Walsh*

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Dated: July 15, 2011

RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is related to the following pending matter: *Wyeth v. Intellipharmaceutics International Inc. et al.*, Civil Action No. 10-561, pending before the Honorable Leonard P. Stark, U.S.D.J. in the United States District Court, District of Delaware.

I certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding other than the above referenced matter, nor are there any non-parties known to Plaintiff that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

DATED: July 15, 2011

By: */s Liza M. Walsh*

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(973) 535-0500
Attorneys for Plaintiff Wyeth LLC

RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, injunctive relief.

DATED: July 15, 2011

By: */s Liza M. Walsh*

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